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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/451,180	11/29/1999	WILFRIED FISCHER	29473/10458	8712

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/451,180

Applicant(s)

FISCHER ET AL.

Examiner

Isis Ghali

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,16-19 and 21-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,16-19 and 21-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' amendment D, filed 10/26/2001; and revocation of power of attorney/power of attorney, request for extension of time and request under 1.114, all filed 1/24/2002.

Claims 1, 16-19, 20-22 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/24/2002 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Claim 18 is further adding the tackifiers to claim 1 and the tackifiers can be copolymers while claim 1 has closed language regarding the copolymer.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 16-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,965,155 ('155) or US 5,869,089 ('089) in view of any of US 4,753,648 ('648) or US 4,358,494 ('494).

US '155 discloses a multi-layered transdermal patch for the treatment of migraine, said patch comprising contact adhesive layer comprising clonidine in base comprising copolymer of 2-ethylhexyl acrylate and vinyl acetate. The adhesive layer further comprises filler, a tackifier and a plasticizer (skin protective substance). The transdermal plaster comprising an impermeable backing and a protective layer, which is removed prior to use, such a layer is made of siliconized paper. The adhesive layer has weight per unit area of 125 mg/m^2 . See the abstract; col.1, lines 8-15, 54; col.3, lines 12-43, 58-62; col.4, lines 5-9, 30-37, 65-67; col.5, lines 16-17.

US '089 discloses a transdermal delivery device to treat drug addiction, said TTS comprising drug adhesive reservoir containing clonidine and the copolymer of ethylhexyl acrylate and vinyl acetate; backing of polyester; and silicone based release liner. The TTS is inherently multi-layered. See abstract; col.1, lines 56-67; col.2, lines 1-11; col.3, lines 14-20, 34, 40-42; col.4, lines 12-35.

The references, however, teach the copolymer comprising monomers other than 2-ethylhexyl acrylate and vinyl acetate, and do not teach the material of the backing or the amount of the clonidine.

US '648 teaches an adhesive composition having a high shear and low peel resistance. The adhesive composition comprises vinyl acetate-2 ethylhexyl acetate copolymer (col.5, lines 41-48). The adhesive is used in personal care articles.

US '494 teaches a pressure sensitive adhesive with low coast and slip resistance. The pressure sensitive adhesive comprises copolymer of polyacrylate ester such as 2-ethylhexyl acrylate with vinyl monomer such as vinyl acetate (col.2, lines 63, 67; col.6, lines 65-68; col.7, lines 1-6).

It is within the skill in the art to select different materials for the backing and protective layers such as plastic, polyester, woven and non-woven fabric, and they all well known in the art. It is within the skill in the art to select optimal parameters such as ratios and weight percents of components as well as determining the dose of delivering a medication in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, the weight percents of clonidine and its delivery rate instantly claimed are not considered critical absent evidence showing unexpected and superior results.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to produce a transdermal device of any of US '155 or US '089 to deliver clonidine and limit the copolymer of the adhesive layer into monomers of 2-ethylhexyl acrylate and vinyl acetate as taught by any of US '684 or US '494 with

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reasonable expectation of success of the device to deliver clonidine. Motivation would arise from the teaching of US '648 that the copolymer of vinyl acetate and 2-ethylhexyl acrylate has high shear and low peel resistance or from the teaching of US '494 of the copolymer has low coast and slip resistance.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600